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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/666,412 | 09/18/2003 | Joseph Wang | 37000-UT-0206 | 8931 |
| 5179 | 7590 | 04/24/2006 | EXAMINER | |
| PEACOCK MYERS, P.C. 201 THIRD STREET, N.W. SUITE 1340 ALBUQUERQUE, NM 87102 | | | DO, PENSEE T | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1641 | |

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/666,412

Applicant(s)

WANG ET AL.

Examiner

Pensee T. Do

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,7-11,13-18,20-31 and 33-40 is/are pending in the application.
- 4a) Of the above claim(s) 33-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,7-11,13-18 and 20-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-3,5,7-11,13-18,20-31 and 33-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry & Claims Status

The amendment filed on January 25, 2006 has been acknowledged and entered.

Claims 1-3, 5, 7-11, 13-18, 20-31, 33-40 are pending.

Claims 33-40 are withdrawn from further consideration.

Claims 1-3, 5, 7-11, 13-18, 20-31 are being examined.

Withdrawn Rejection(s)

Rejection of claim 5 under 103 in the previous office action is withdrawn herein.

Rejection under 102 by Knoll is withdrawn herein.

Rejection under 102 by Bamdad is withdrawn herein.

Maintained Rejection(s)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7, 10-11, 13, 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Brooks et al. (US 5,753,517).

Brooks teaches a quantitative immunochromatographic assay for measuring the amount of an analyte and an apparatus for use in the assay. The method comprises providing a microsphere having an incorporated electroactive marker and a first member of a specific binding pair attached to the microsphere wherein the microsphere

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is not a liposome. (see col. 5, lines 13-18). The microsphere can be colloidal gold, sulphur, selenium, barium sulfate, iron sulfate, metal iodate, silver halide, silica particle or organic polymer latex particles. The particles are polystyrene latex beads. These polymeric microspheres are insoluble in an aqueous solution. The particles are labeled with electroactive agents such as ferrocyanite to facilitate detection. The particles are coated with an agent that specifically binds to the analyte. (see col. 4, line 60-col. 5, line 33). The second member of the binding pair is bound to a substrate (see col. 6, lines 50-64). The analyte is incubated with the microsphere. (see col. 4, lines 24-47). The specific binding pair complex is an antigen/antibody. (see col. 3, lines 58-67). The method further comprises releasing the electroactive marker from the microsphere by solubilizing the microsphere. Electrochemical testing comprises measurement of one or more electrical quantities in relationship to one or more chemical parameters such as current, potential or charge by anodic stripping voltammetry. (see col. 7, lines 15-19).

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 7-11, 14-17, 20-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bamdad et al. (US 2003/0059955) in view of Brooks et al. (US 5,753,517).

Bamdad teaches a method of detection of the presence of a member of a specific binding pair, the method comprising: providing semiconductor nanocrystal (nanoparticle or redox-active molecules such as ferrocene derivatives (metallocene)) embedded within or attached to a microparticle such as a colloidal particle. (see [0058]). Colloidal particles include self-suspendable/insoluble particles including organic, polymeric, and metal particles. The polymeric particle/microsphere can be polystyrene. (see [0034]; selecting for the microsphere by formation of a specific binding pair complex and electrochemically testing for the electroactive marker/nanocrystal. The first member of a specific binding pair is attached to the microsphere/particle through covalent bond and a functional group. The first member of a specific binding pair is attached to the microsphere and a second member of the specific binding pair attaches to a substrate such as a magnetic bead. Binding partners can be two different types of antibodies, proteins, enzyme/substrate, antibody/antigen, antibody/hapten, carrier protein/substrate, receptor/hormone, etc. (see ([0048]; [0031]; [0034]; [0063]; [0074] lines 1-13; [0073])). Regarding claim 20, Bamdad teaches providing a second nanoparticle different from the first nanoparticle, attaching the second binding pair member specific to the second analyte to the second microsphere/nanoparticle; incubating the first microsphere and the second microsphere in a solution comprising the sample; selecting the first and second microspheres by formation of specific binding pair complexes; and electrochemically testing the first electroactive marker and the second electroactive marker (claim 30), (see [0013], [0073]; example 4 [0080], [0081]).

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Regarding claims 27-29, the electroactive markers are ferrocene derivatives (metallocenes), nanoparticles or metals (see [0058]).

However, Bamdad fails to teach releasing the first electroactive marker and the second electroactive marker from the first and second microspheres respectively; and detecting via voltammetry or amperometry.

Brooks has been discussed above.

It is well known that when using electroactive agent as a label, such electroactive agent must be released in order to quantitate the analyte associated with it. (see Brooks). Since Bamdad also teaches using electroactive agent embedded within a microsphere, it would have been obvious to one of ordinary skills in the art to release such electroactive agent at detection as taught by Brooks in the method of Bamdad. Detection of electroactive agent is usually carried out by anodic stripping voltammetry as taught by Brooks. Thus, it would have been obvious to one of ordinary skills in the art to detect by anodic stripping voltammetry as taught by Brooks for electrochemical analysis as taught by Bamdad since Bamdad teaches detection of the electroactive agent by electrochemical analysis.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bamdad in view of Brooks as applied to claim 1 above, and further in view of Barbera-Guillem (Us 6,680,211).

Bamdad and Brooks have been discussed above.

However, they both fail to teach incubation of a polymeric microsphere in an organic solvent including an electroactive marker.

Barbera-Guillem teaches polymeric microspheres incubated with an organic solvent comprising fluorescent nanocrystals (electroactive agent). In this organic solvent, the polymeric microspheres are swelled to entrap the fluorescent nanocrystals. (see col. 11, lines 23-55).

It is well known that in order for a polymeric microsphere to entrap an indicator compound, such microsphere must be placed in an organic solvent so that the polymeric microsphere swells up and entrap the indicator compound or whatever it is needed to be entrapped. It would have been obvious to one of ordinary skills in the art to incubate the polymeric microspheres entrapping an electroactive agent of Bamdad and Brooks in an organic solvent to facilitate entrapment of the electroactive agent/nanocrystals in the polymeric microspheres since Brooks teaches that nanocrystals are entrapped in polymeric microspheres.

Response to Arguments

Applicant's arguments filed January 25, 2006 have been fully considered but they are not persuasive.

Regarding the Brooks reference, Applicants argue that Brooks teaches that the particles are labeled with an electroactive marker and the particle is affixed to a substrate and therefore are not in fluid suspension as at least one member of the binding pair complex is embedded in a fixed substrate. This teaching is contradictory to the claimed invention, which recites that "selecting for the microsphere by formation of a specific binding pair complex in fluid suspension".

Although Brooks teaches that the particles are embedded in a contact region, these particles (coated with antibody) are maintained under conditions allowing analyte in the fluid sample to bind to the antibody-coated particles imbedded in the contact region. (see col. 6, lines 41-45). Capillary action of the fluid from the fluid sample mobilizes the contacted antibody-coated particles and moves the contacted antibody-coated particles along the membrane to a detection zone on the membrane. (see col. 6, lines 50-53). Thus, the formation of the binding pair complex is in fluid suspension.

Regarding the Bamdad reference, Applicants argue that Bamdad fails to teach electroactive markers encapsulated within a microsphere, releasing an electroactive marker, and detecting the electroactive marker after release via voltammetry or amperometry. Instead Bamdad teaches loading the surface of the crystals with a label, and detecting the label via optical detection of electromagnetic radiation in a narrow wavelength band.

Applicants' attention is directed to Bamdad, col. 6, [0058] where Bamdad teaches that the nanocrystals are embedded within a larger structure such as a colloidal particle. Regarding the steps of releasing and detecting via voltammetry, those limitations are taught in the secondary reference, Brooks. Bamdad teaches detection by electrochemical measurement. Brooks teaches detection by voltammetry and releasing the electroactive marker. (see col. 7, lines 2-19).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
April 14, 2006


LONG V. LE
SUPERVISORY PATENT EXAMINER
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04/17/06